

WO 03/049667

PCT/IB02/05516

We Claim:

1. A method of treating cancer comprising administration of a formulation which is prepared using mycobacterium w or a pharmaceutical composition obtained from mycobacterium w alone or in combination and also with or without adjuvants to a subject who has been suffering from cancer.
2. The product as claimed in claim 1 contain mycobacterium w is killed mycobacterium w.
3. The Mycobacterium w as claimed in claim 1 and 2 is killed by physical method like heat radiation most preferably by heat in form of autoclaving.
4. The product as claimed in claim 1 is obtained from mycobacterium w by sonication.
5. The product as claimed in claim 1 is obtained from mycobacterium w by extraction.
6. The product as claimed in claim 1 and 5 is obtained from mycobacterium w is extracted by organic solvents.
7. The product as claimed in claim 1, 5 and 6 is extracted using solvent selected from chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea, Hexane and like.
8. The adjuvants as claimed in claim 1 is selected from mineral oil, mineral oil and surfactant, Ribi adjuvant, Titer-max, syntax adjuvant formulation, aluminium salt adjuvant, nitrocellulose adsorbed antigen, immune stimulating complexes, Gebru adjuvant, super carrier, elvax 40w, L-tyrosine, monatanide (manide-oleate compound), Adju prime, Squalene, Sodium phthalyl lipopoly saccharide, calcium phosphate, saponin, melanoma antigen, muramyl dipeptide (MDP) and like.
9. The formulation as claimed in claim 1 contains surfactant.
10. The surfactant as claimed in claim 9 can be a Tween 80.
11. The amount of surfactant as claimed in claim 9 and 10 is upto 0.4% preferably 0.1%.
12. The formulation as claimed in claim 1 containing mycobacterium w or obtained from mycobacterium w or combination of both with or without adjuvants helps in amelioration of symptoms of cancer.
13. The formulation as claimed in claim 1 containing mycobacterium w or obtained from mycobacterium w or combination of both with or without adjuvants are capable of causing regression or even complete control of cancer.
14. The Mycobacterium w as claimed in claim 1,2,3,4,5,6 is a non-pathogenic, fast growing cultivable, atypical mycobacterium, with biochemical properties and growth characteristics resembling those belonging to Runyons group IV class of Mycobacteria in its metabolic and growth properties but is not identical to those strains currently listed in this group.
15. Mycobacterium w as claimed in claim 1 is urease negative, does not hydrolyse tween 80, does not produce niacin, provides strong positive response to nitrate reduction test.

BEST AVAILABLE COPY

WO 03/049667

PCT/IB02/05516

16. The method as claimed in claim 1 for management of cancer is effective when used alone or combination with other modalities of cancer treatment like chemotherapy, radiotherapy, surgery.
17. The method as claimed in claim 1 for management of cancer is effective in improving quality of life in patient who are suffering from cancer.
18. The improvement in quality of life as claimed in claim 14 is obtained in absence as well as presence of other modes of treatment.
19. The method as claimed in claim 1 for management of cancer is effective in amelioration of symptoms associated with cancer.
20. The method as claimed in claim 1 for management of cancer is effective in decreasing the burden of cancer tissue.
21. The decrease in burden of cancer tissue as claimed in claim 17 is obtained in absence as well as presence of other modes of therapy.
22. The cancerous tissue as claimed in claim 17 can be a primary or a secondary (metastatic) lesion.
23. The method as claimed in claim 1 is effective in reducing side effects of other cancer therapies like radiotherapy, chemotherapy.
24. The administration of formulation as claimed in claim 1 is by parental route.
25. The administration as claimed in claim 1 and 17 is by intramuscular subcutaneous, intradermal route and like but preferably by intradermal route.
26. The amount of mycobacterium w administered at a time to a subject as claimed in claim 1 is equal to or more than 1×10^6 mycobacterium w.
27. The amount of mycobacterium w administered at a time to a subject as claimed in claim 1 is equal to or more than 10^7 mycobacterium w.
28. The amount of mycobacterium w administered at a time to a subject as claimed in claim 1 is most preferably 1×10^6 to 1×10^{10} mycobacterium w.
29. The process of manufacturing a pharmaceutical composition useful for management of cancer comprises of incorporating cells of mycobacterium w along with pharmaceutically acceptable carrier and optionally a preservative in a single formulation wherein cells of mycobacterium w are not alive.
30. The pharmaceutically acceptable carrier as claimed in claim 1 is added in a way so as to have more than or equal to 1×10^6 mycobacterium w in a unitary dosage, more preferably equal to or more than 1×10^7 mycobacterium w in unitary dosage most preferably between 1×10^6 to 1×10^9 cells of mycobacterium w in a unitary dosage form.
31. The process of manufacturing a pharmaceutical composition useful for management of cancer comprising the steps of incorporating disrupted cells of mycobacterium w along with pharmaceutically acceptable carrier and optionally a preservative.
32. The process of manufacturing a pharmaceutical composition useful for management of cancer comprising the steps of incorporating solvent extraction of mycobacterium w along with pharmaceutically acceptable carrier and optionally a preservative.
33. The process of manufacturing a pharmaceutical composition useful for management of cancer comprising of incorporating enzymatic

BEST AVAILABLE COPY

WO 03/049667

PCT/IB02/05516

extraction of mycobacterium w along with pharmaceutically acceptable carrier and optionally a preservative

34. The process of manufacturing a pharmaceutical composition useful for management of cancer comprising admixing product of claim 1 with product of claim 31 and/or claim 32 and/or claim 33.
35. The process of manufacturing a pharmaceutical composition useful for management of cancer comprise of adding adjuvant to product of claim 1, claim 4, claim 6, claim 8 or claim 10.
36. The adjuvant as claimed in claim 17 is selected from mineral oil, mineral oil and surfactant, Ribi adjuvant, Titer-max, syntax adjuvant formulation, aluminium salt adjuvant, nitrocellulose adsorbed antigen, immune stimulating complexes, Gebru adjuvant, super carrier, elvax 40w, L-tyrosine, monatanide (manide -oleate compound), Adju prime, Squalene, Sodium phthalyl lipopoly saccharide, calcium phosphate, saponin, melanoma antigen, muramyl dipeptide(MDP) and like.

BEST AVAILABLE COPY